

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/014919

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl.⁷ C07K16/00, 1/02, C12N15/09

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl.⁷ C07K1/00-16/46, C12N15/00-90

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
JICST FILE (JOIS), EUROPAT (QUESTEL), MEDLINE/BIOSIS/WPIDS (STN)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	JP 07-502497 A (THE WELLCOME FOUNDATION LTD.), 16 March, 1995 (16.03.95), & WO 1993/008837 A1 & US 5792838 A	1-4
Y	WO 1999/037329 A1 (AKTIEBOLAG), 29 July, 1999 (29.07.99), & SE 9800170 A	1-4
Y	WO 2000/066160 A1 (Yamanouchi Pharmaceutical Co., Ltd.), 09 November, 2000 (09.11.00), & EP 1174148 A1	1-4

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
18 November, 2004 (18.11.04)Date of mailing of the international search report
07 December, 2004 (07.12.04)Name and mailing address of the ISA/
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	JP 06-189781 A (Mitsui Toatsu Chemicals, Inc.), 12 July, 1994 (12.07.94), (Family: none)	1-4
A	B. CHEN, et al., Strategies To Suppress Aggregation of Recombinant Keratinocyte Growth Factor during Liquid Formulation Development, 1994, 83(12), p.1657-61	1-4

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Box No. II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 1-4 (part)
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

See extra sheet.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

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Continuation of Box No.II-2 of continuation of first sheet (2)

Claims 1-4

The degree of the "low temperature" in the above claims is indefinite, so that the claims are not clear.

The stabilization of proteins is ascertained in Examples only at 7°C, 4°C, and 1°C, so that whether the methods of the above claims are effective at temperatures higher than 7°C or lower than 1°C or not is unclear. Thus, the inventions of the above claims are inadequately supported and are not disclosed in a manner sufficiently clear and complete for the inventions to be carried out by a person skilled in the art.

No search has been made on the inventions which are inadequately supported by the description and are not clearly and completely disclosed in the description.

Claims 1, 2, 4

It is unclear what "proteins" can be stabilized by the addition of a citrate buffer in addition to "IgM" whose stabilization at low temperature is ascertained in Examples. Thus, the inventions of the above claims are inadequately supported by the description and are not disclosed in a manner sufficiently clear and complete for the inventions to be carried out by a person skilled in the art.

No search has been made on the inventions which are inadequately supported by the description and are not clearly and completely disclosed in the description.